

Membership Balance Plan

ENVIRONMENTAL PROTECTION AGENCY
1. FEDERAL ADVISORY COMMITTEE NAME <i>State the legal name of the FAC</i>
Human Studies Review Board
2. AUTHORITY <i>Identify the authority for establishing the FAC</i>
Agency Authority, Deputy Administrator approval document.
3. MISSION/FUNCTION <i>Describe the mission/function of the FAC</i>
The Human Studies Review Board (HSRB) will provide advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research. The major objectives are to provide advice and recommendations on: Research proposals and protocols; reports of completed research with human subjects; and how to strengthen EPA's programs for protection of human subjects of research.
4. POINTS OF VIEW <i>Based on understanding the purpose of the FAC,</i> <i>(a) describe the process that will be used to ensure the committee is balanced, and identify the categories</i> <i>(b) consider identifying an anticipated relative distribution of candidates across the categories; and</i> <i>(c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members</i>
The HSRB will be composed of approximately ten (10) members who will serve as Special Government Employees (SGE) or Regular Government Employees (RGE). In selecting members, EPA will consider candidates from the environmental scientific/technical fields, human health care professionals, academia, industry, public and private research institutes or organizations, other governmental agencies, and other relevant interest areas. The HSRB membership will include experts in relevant scientific or technical disciplines such as bioethics, biostatistics, human health risk assessment and human toxicology.

5. OTHER BALANCE FACTORS

List any other factors EPA identifies as important in achieving a balanced FAC

Geographic location may be considered.

6. CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance.

The

summary should:

- (a) describe the process*
- (b) identify EPA key staff involved (by position, not name)*
- (c) briefly describe how FAC vacancies, if any, will be handled by EPA*
- (d) state the membership term limit of FAC members, if applicable*

Approximately 8 months prior to expiration of committee members' terms the DFO meets with EPA's Office of Diversity, Advisory Committee Management, and Outreach (ODACMO) to discuss the outreach plan, establish a timeline, and other issues concerning the membership package. After approval of the outreach plan the DFO conducts outreach for new members in accordance with the plan.

The DFO solicits candidate names through a Federal Register notice and from individuals who are actively engaged in interests relating to environmental scientific/technical fields, human health care professionals, academia, industry, public and private research institutes or organizations, other governmental agencies, and other relevant interest areas. The HSRB membership will include experts in relevant scientific or technical disciplines such as bioethics, biostatistics, human health risk assessment and human toxicology.

After a review of the pool of nominees, a determination is made to consider whether additional outreach is needed. Each candidate is researched to determine whether the person is a federally registered lobbyist. The DFO develops a draft grid of nominees, including at least one additional candidate for each point of view for the function the committee is to perform.

A balance review of the proposed membership is then conducted by ODACMO and the FACA Attorney. Different levels of EPA managers then review the draft package for questions or comments before the final package is prepared.

Formal letters of invitation to serve on the HSRB will be extended by the Administrator or Deputy Administrator of EPA. This cycle will be repeated for any occurring vacancies. Members are usually appointed for a two-year or three-year term. Generally, members may be reappointed for a total of 6 years.

7. SUBCOMMITTEE BALANCE

Subcommittees subject to FACA should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different*

**This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*

EPA plans to use the process that is used to determine advisory committee member balance for the parent (Tier 1) Federal advisory committee for any Tier 2 subcommittee(s) that may be created.

8. OTHER

Provide any additional information that supports the balance of the FAC

Not applicable.

9. DATE PREPARED/UPDATED

March 7, 2014
July 29, 2015 (amended)